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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,204	04/02/2004	Nagi G. Ayad	10498-00067	3911
22910 7590 06/15/2007 BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			EXAMINER LEE, JAE W	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,204	Applicant(s) AYAD ET AL.	
	Examiner Jae W. Lee, Ph.D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 and 27-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

In response to the previous Office actions, a non-Final rejection (mailed on 12/29/2006), Applicants filed a response and amendment received on 03/29/2007. Said amendment, amended Claims 1-3, 5 and 6. Claims 1-51 are at issue and present for examination

Applicants' arguments filed on 10/27/2006, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

It is noted by the Examiner that Claims 14-25 and 27-51 were withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention, in the previous Office actions, a non-Final rejection (mailed on 12/29/2006).

Withdrawn-Objections to the Specification

The previous objection of the title is withdrawn by virtue of Applicant's amendment.

Withdrawn-Claim Objections

The previous objection of claims 1-3 (4-13 and 26 dependent therefrom) with respect to recitations of "Tome-1," "SCF," and "wee1," is withdrawn by virtue of Applicant's amendment.

Withdrawn-Claim Rejections - 35 USC § 112

The previous rejection of Claim 2 under of 35 U.S.C. 112, second paragraph, for lacking antecedent basis is withdrawn by virtue of Applicant's amendment.

The previous rejection of Claim 3 under of 35 U.S.C. 112, second paragraph, for with respect to "the nucleic acid molecule encodes a nucleotide sequence" is withdrawn by virtue of Applicant's amendment.

Maintained-Claim Rejections - 35 USC § 112

The previous rejection of Claims 1, 2, 7-13 and 26 under of 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that Claim 1 and its dependent claims are directed to one or more "Tome-1 activities" from (1)-(12) as listed on pg. 12 of their Remarks filed on 03/29/2007. However, claim 1 is not limited to those activities listed under (1)-(12). As such, the claim 1 (2, 7-13 and 26 dependent therefrom)

remains to be unclear with respect to whether to one or more "Tome-1 activities" exclude other biological activities of Tome-1 or not.

The previous rejection of Claim 2 under of 35 U.S.C. 112, second paragraph, with respect to "wee1" is maintained because describing what is known about "wee1 ubiquitinylation" or "wee1 degradation" does not define what "wee1" is.

The previous rejection of Claim 2 under of 35 U.S.C. 112, second paragraph, with respect to "SCF complex component" is maintained because although the "SCF complex" may be a complex of SKp-1, Cul-1, Rbx and the F box substrate receptor protein, the claim, as amended, does not recite that SCF complex component is a complex of such. Therefore, as the claim is written, SCF complex component can be a short peptide fragment of any of its alleged components, i.e., SKp-1, Cul-1, Rbx and the F box substrate receptor protein.

The previous rejection of Claim 2 under of 35 U.S.C. 112, second paragraph, with respect to "SCF complex component activity" or "activities" is maintained because although some of their activities may be well-known in the art as shown Attachment D, it is not clear whether other biological activities of "SCF complex component" are excluded or encompassed by the "SCF complex component activity" or "activities."

The previous rejection of Claims 1-13 and 26 under 35 U.S.C. 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that the specification at page 13, lines 1-7 describes several examples of species that the genus embraces, i.e., human, mouse and *Xenopus* Tome-1 polynucleotides and their corresponding polypeptides which have one or more Tome-1 activities. Applicants also allege that specific Tome-1 activities are taught on page 17, lines 7-12. However, these are not adequate written description of the genus claimed. For instance, what about the unicellular and multi-cellular prokaryotes, which have vastly different sequences of DNA, proteins and cell-cycles, i.e., lacking mitosis, that are encompassed by the claims? Furthermore, claims, as amended, are not limited to those of Tome-1 activities listed on pg. 16 of the Remarks, and therefore, all other non-biological and biological activities of Tome-1 are still encompassed by the claims.

The previous rejection of Claims 1-13 and 26 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that determining whether the nucleic acid sequence encodes a polypeptide having the claimed sequence identity and has one or more Tome-1 activities would involve "only *routine screening*." However, the argument is not sufficient to overcome this rejection, because as described above for claims as currently amended, it would be undue experimentations for one of skill in the art to test all of the representative DNA of all organisms, i.e., prokaryotes, eukaryotes, as well as archaic species for which just obtaining DNA samples might be difficult, for having all of

biological and non-biological activities of Tome-1, especially when many of these DNA samples come from organisms that don't undergo mitosis.

Maintained-Claim Rejections - 35 USC § 102

The previous rejection of Claims 1-3, 5-13 and 26 under 35 U.S.C. 102(b) as being anticipated by Walker et al. (WO/2002/018575) is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the reasons described below.

Applicants argue that the previous Office Action provides no evidence of, such as a sequence alignment, that SEQ ID NO: 3 of Walker et al. shares 97% homology with Applicant's SEQ ID NO: 5. The Examiner has provided the sequence search results showing the sequence alignment results in SCORE (please see sequence search results available in SCORE, especially under US-10-817-204-5, which is specific for Applicants SEQ ID NO: 5). It is noted by the Examiner that the reference of Walker et al. is listed in the aforementioned file, US-10-817-204-5 in SCORE, as Result No. 7. It is further noted by the Examiner that there are 8 other sequences within Results Nos. 1-9 that share % sequence homology of greater than 60% with Applicant's SEQ ID NO: 5.

Furthermore, Walker et al. teach that SEQ ID NO: 3 is a cDNA, and by virtue of the definition of cDNA, it is complementary to mRNA, which encodes a polypeptide when transcribed, having one or more Tome-1 activities (see maintained 112 2nd paragraph rejection above). Therefore, whether or not SEQ ID NO: 3 encodes CDC23, which modulates cell-cycle, is immaterial to the validity of this rejection given the

interpretation of "one or more Tome-1 activities" (see maintained 112 2nd paragraph rejection above). Also, the SEQ ID NO: 3 has greater than 97 % sequence identity with Applicant's SEQ ID NO: 5, and for that reason, the encoded polypeptide will have at least 60 % sequence homology to Applicant's SEQ ID NO: 2.

Conclusion

Claims 1-13 and 26 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered section in this Office action to be fully responsive in prosecution.

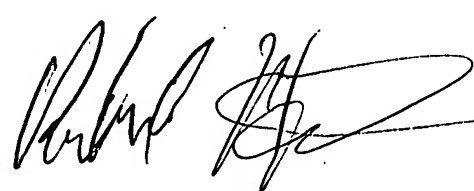
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Patent Examiner: Jae W. Lee, Ph.D.
RICHARD HUTSON, PH.D.
PRIMARY EXAMINER